REMARKS

Claims 1-32 were pending in the subject application. Applicants have hereinabove cancelled claims 3-7, 9, 16, and 19, without prejudice to refiling these claims in future application that claims the benefit of the subject application's filing date, amended claims 1, 8, 10, 17, 18, 27, 28, and 32, and added new claims 33-48. Accordingly, claims 1, 2, 8, 10-15, 17, 18, and 20-48 are pending in the subject application.

Before addressing the substance of the Office Action, applicants point out that Information Disclosure Statements were filed in connection with the subject application on December 20, 2001, March 6, 2002, and October 15, 2002. Applicants request that all documents cited therein be considered and that initialed Forms 1449 be returned to applicants to evidence such consideration.

Claims 1-2, 4-18, and 19-32 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly not providing enablement for lipase inhibitors in general. While applicants disagree, they fully support the Patent Office's position that the specification is enabling for orlistat. To expedite prosecution, applicants have amended their claims to recite orlistat as the lipase inhibitor, while reserving their right to address this issue and file claims directed to other lipase inhibitors in the future.

In view of applicants' amendments hereinabove, the rejection under 35 U.S.C. § 112, first paragraph, is moot. Reconsideration and withdrawal of the rejection is requested.

Claims 1-5, 7, 7, and 16-32 were rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Hug (U.S. Patent No. 6,6358,522), Hadvary et al. (U.S. Patent No. 4,598,089), Isler et al. (U.S. Patent No. 5,447,953), and/or Bremer (U.S. Patent No. 5,643,874), or in the alternative under 35 U.S.C. § 103(a) as allegedly obvious over the mentioned U.S. patents.

No prior art rejections were made with respect to the combination of lipase inhibitors with the specific bile acid sequestrants claimed in claims 6, 8, and 10. To expedite prosecution, applicants have amended their claims to recite orlistat as the lipase inhibitor (see above) and to limit the claimed bile acid sequestrants to those that the Patent Office has apparently determined to be free of the prior art. Applicants, however, reserve their right to address this issue and file claims directed to other lipase inhibitors and other bile acid sequestrants in the future. In view of applicants' amendments, no rejection under 35 U.S.C. §§ 102(a) and 103(a) remains.

In view of the above, applicants request reconsideration and withdrawal of all rejections under 35 U.S.C. §§ 102(a) and 103(a).

To summarize, applicants request reconsideration, withdrawal of all rejections, and the issuance of a Notice of Allowance.

If a telephone conference would be of assistance in furthering prosecution of the subject application, applicants request that the undersigned attorney be contacted at the number below.

No fee, except the fee for the presentation of additional claims, is required in connection with the filing of this Amendment. If any fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account 08-2525.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Amended Claims:

-- 1. (Amended) A pharmaceutical composition which comprises ~~a lipase inhibitor~~ orlistat and a pharmaceutically acceptable bile acid sequestrant selected from the group consisting of DEAE-cellulose, guanidinoethylcellulose, and DEAE-Sephadex. –

-- 8. (Amended) The composition according to claim ~~7~~ 10, wherein ~~the starch or starch derivative~~ pharmaceutically acceptable bile acid sequestrant is selected from the group consisting of β-cyclodextrin and γ-cyclodextrin. --

-- 10. (Amended) A pharmaceutical composition which comprises orlistat and a pharmaceutically acceptable ~~The composition according to claim 9, wherein the~~ bile acid sequestrant ~~is~~ selected form the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β- cyclodextrin, and γ-cyclodextrin. --

-- 17. (Amended) The composition according to claim 1, wherein the composition comprises (a) from about 5 to about 1000 mg of ~~a lipase inhibitor~~ orlistat and (b) from about 0.1 to about 20 g of ~~a~~ the bile acid sequestrant. –

-- 18. (Amended) The composition according to claim17, which comprises:

(a) from about 5 to about 1000 mg of ~~a lipase inhibitor~~ orlistat;

(b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of DEAE-cellulose, guanidinoethylcellulose, and DEAE-Sephadex;

(c) from about 0.1 to about 10 g of a filler;

(d) from about 0.05 to about 3.0 g of a surfactant;

(e) from about 0.05 to about 2.0 g of a disintegrant;

(f) from about 0.02 to about 2.0 g of a binder;

(g) from about 0.001 to about 1.0 g of a lubricant;

(h) from about 0.1 to about 5.0 g of a flowability enhancer;

(i) from about 0.01 to about 4.0 g of a sweetener; and

(j) and about 0.001 to about 0.5 g of a colorant. --

-- 27. (Amended) A kit for use in the treatment of obesity, which comprises (a) a first component which is ~~a lipase inhibitor~~ orlistat and (b) a second component which is a bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β- cyclodextrin, γ-cyclodextrin, guanidinoethylcellulose, and DEAE-Sephadex, present in oral unit dosage form. --

-- 28. (Amended) A method of treating obesity in an obese patient, which comprises administering to a patient in need of such treatment (a) a therapeutically effective amount of ~~a lipase inhibitor~~ orlistat and (b) a pharmaceutically acceptable bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β- cyclodextrin, γ-cyclodextrin,

guanidinoethylcellulose, and DEAE-Sephadex in an amount effective to reduce gastrointestinal side effects associated with the lipase inhibitor. --

-- 32. (Amended) A method of reducing the gastrointestinal side effects associated with ~~the lipase inhibitor~~ orlistat treatment, which comprises administering to a patient being treated with ~~a lipase inhibitor~~ orlistat an amount of a bile salt sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β- cyclodextrin, γ-cyclodextrin, guanidinoethylcellulose, and DEAE-Sephadex, effective to reduce the side effects associated with the ~~lipase inhibitor~~ orlistat treatment. –

New Claims:

-- 33. (New) The composition according to claim 10, wherein the composition comprises (a) from about 5 to about 1000 mg of orlistat and (b) from about 0.1 to about 20 g of the bile acid sequestrant. --

-- 34. (New) The composition according to claim 33, which comprises:

(a) from about 5 to about 1000 mg of orlistat;

(b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β- cyclodextrin, and γ-cyclodextrin;

(c) from about 0.1 to about 10 g of a filler;

(d) from about 0.05 to about 3.0 g of a surfactant;

(e) from about 0.05 to about 2.0 g of a disintegrant;

(f) from about 0.02 to about 2.0 g of a binder;

(g) from about 0.001 to about 1.0 g of a lubricant;

(h) from about 0.1 to about 5.0 g of a flowability enhancer;

(i) from about 0.01 to about 4.0 g of a sweetener; and

(j) and about 0.001 to about 0.5 g of a colorant. –

-- 35. (New) The composition according to claim 13, wherein the composition comprises (a) from about 5 to about 1000 mg of orlistat and (b) from about 0.1 to about 20 g of the bile acid sequestrant. --

-- 36. (New) The composition according to claim 35, which comprises:

(a) from about 5 to about 1000 mg of orlistat;

(b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose, β- cyclodextrin, and γ-cyclodextrin;

(c) from about 0.1 to about 10 g of a filler;

(d) from about 0.05 to about 3.0 g of a surfactant;

(e) from about 0.05 to about 2.0 g of a disintegrant;

(f) from about 0.02 to about 2.0 g of a binder;

(g) from about 0.001 to about 1.0 g of a lubricant;

(h) from about 0.1 to about 5.0 g of a flowability enhancer;

(i) from about 0.01 to about 4.0 g of a sweetener; and

(j) and about 0.001 to about 0.5 g of a colorant. --

-- 37. (New) The compositions according to claim 33, wherein the orlistat is present in an amount of from about 10 to about 500 mg. --

-- 38. (New) The composition according to claim 37, wherein the orlistat is present in an amount of about 120 mg. --

-- 39. (New) The composition according to claim 33, wherein the orlistat is present in an amount of from about 20 to about 100 mg. --

-- 40. (New) The composition according to claim 39, wherein the orlistat is present in an amount of about 60 mg. --

-- 41. (New) The composition according to claim 33, wherein the bile acid sequestrant is present in an amount of from about 0.5 to about 10 g. --

-- 42. (New) The composition according to claim 41, wherein the bile acid sequestrant is present in an amount of from about 1 to about 5 g. --

-- 43. (New) The compositions according to claim 35, wherein the orlistat is present in an amount of from about 10 to about 500 mg. --

-- 44. (New) The composition according to claim 43, wherein the orlistat is present in an amount of about 120 mg. --

-- 45. (New) The composition according to claim 43, wherein the orlistat is present in an amount of from about 20 to about 100 mg. --

-- 46. (New) The composition according to claim 45, wherein the orlistat is present in an amount of about 60 mg. --

-- 47. The composition according to claim 35, wherein the bile acid sequestrant is present in an amount of from about 0.5 to about 10 g. --

-- 48. (New) The composition according to claim 47, wherein the bile acid sequestrant is present in an amount of from about 1 to about 5 g. --